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Congress of the United States

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December 3, 2010

The Honorable Margaret A. Hamburg, M.D.
Commissioner
Food and Drug Administration
5600 Fisher's Lane
Rockville, MD 20857

Dear Commissioner Hamburg:

We write to request information from the Food and Drug Administration (FDA) concerning a November 17, 2010, article in *The Gazette (Bethesda/Potomac/Chevy Chase)*, "FDA Employees Balk at Ban on Agricultural Pursuits." This article discusses a memorandum sent to employees on September 29, 2010, instructing them to sell their farming interests within 60 days in order to comply with conflict of interest rules pertaining to FDA employees (*see* attachment). Apparently, the decision to restrict farm ownership by employees of FDA – while providing them with a *mere 60 days* to divest themselves of any such interests – is the result of a reinterpretation of regulations appearing in the Supplemental Standards of Ethical Conduct for Employees of the Department of Health and Human Services that have been on the books since July 1996, and forbid FDA employee possession of a "financial interest in a significantly regulated organization." "Significantly regulated organization" is defined to include any organization that derives ten percent or more of its annual gross sales from the sale of FDA-regulated products (61 FR 39758).

We recognize that FDA has a compelling need to monitor and, where necessary, impose reasonable restrictions on the financial and employment ties between FDA employees and the vast number of entities regulated by the agency. However, we are concerned that the actions demanded by the September 29 memorandum may be unreasonable, if not draconian, both in substance and in form. We are not aware of any actual case or problem justifying the reinterpretation. Thus, it is a mystery to us how these FDA employees who own family farms, many of whom have reported their farming to the agency through financial disclosures for 14

years, now suddenly stand to potentially harm “public confidence in the impartiality or objectivity with which FDA programs are administered” or to otherwise raise serious conflict of interest concerns under the standards of ethical conduct for employees of the executive branch (61 FR 39758). At the same time, we question the sensibility that any such demand, which is based on a regulation dating back *14 years* and would surely impose a severe administrative and financial burden on certain FDA employees, must be carried out within a *60-day period*. Without FDA being transparent about the evidentiary need for this reinterpretation, this has the appearance of a solution in search of a problem.

We respectfully request that you supply us with a copy of the aforementioned memorandum to FDA employees dated September 29, 2010, and any documents referenced in the memorandum within two weeks of the date of this letter. We also ask that responses to the following questions be provided within two weeks of the date of this letter:

1. How did the reinterpretation of FDA’s employee conflict of interest rules, as reflected in the September 29 memorandum, come about? In your answer, please discuss how FDA’s legal interpretations on what constitutes an FDA-regulated product have evolved over the 14-year period between the publication of these supplemental standards and the drafting of the September 29, 2010, memorandum.
2. What was the basis for FDA to reject measures such as recusal that are short of divestiture to address any ethics concerns?
3. What was the reasoning behind the September 29 memorandum’s demand that the FDA employee’s farm ownership interests be sold within 60 days? On what basis was the 60-day figure chosen, and not, for example, 12 months or 2 years?
4. How many FDA employees stand to be affected by the memorandum’s demand that they divest from their farm ownership interests within 60 days? Shouldn’t FDA have known how many of its employees could be potentially affected by a ban on farming *prior* to the distribution of the September 29 memorandum?
5. Has FDA given any consideration to the financial or other harms that may be incurred by employees unable to carry out the demands of the September 29 memorandum within the 60-day period? Between September 29, 2010 and the present time, have any FDA employees already experienced financial losses due to a rush to sell or lease their land pursuant to the September 29 memorandum’s instructions?
6. Until what date will the enforcement of the reinterpretation of FDA’s conflict of interest rules governing FDA employees be held in abeyance? What procedures are in place to review and/or renew this enforcement suspension prior to arrival of that date?

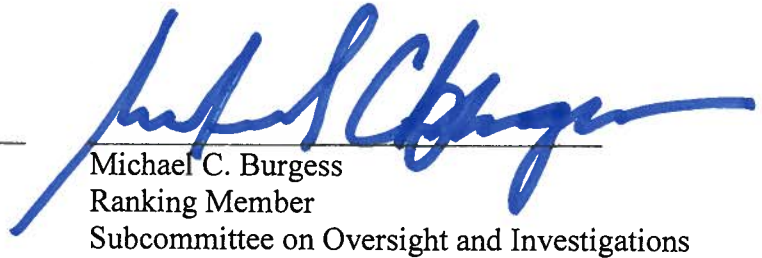
7. What steps has FDA taken to ensure that employees affected by the reinterpretation, and any future modifications, will be notified thereof in full, and within a reasonable period of time?

We appreciate your attention to this important issue. Please do not hesitate to contact the Minority Committee staff at (202) 225-3641 if you have any questions about this matter.

Sincerely,



Joe Barton
Ranking Member



Michael C. Burgess
Ranking Member
Subcommittee on Oversight and Investigations

cc: The Honorable Henry A. Waxman, Chairman

The Honorable Bart Stupak, Chairman
Subcommittee on Oversight and Investigations

Attachment

Wednesday, Nov. 17, 2010

FDA employees balk at ban on agricultural pursuits

by Margie Hyslop | Staff Writer

Just after part-time farmer Lonnie Luther chopped corn silage on his Damascus farm this fall, he got a letter from his employer — the U.S. Food and Drug Administration — that told him that this year's harvest could be his last.

The Sept. 29 memo said the lifelong farmer — who bought his first farm in Montgomery County a few years after he went to work for the FDA in 1974 — had 60 days to sell his farming interests because selling food has been deemed to violate conflict of interest laws governing FDA employees.

Because farms sell food and the FDA regulates it, the agency has decided employees whose positions require them to file financial disclosures are not allowed to work for the agency and "have a financial interest in a farming operation."

"There's no way I can parlay my work into a conflict of interest," said Luther, a special assistant to director of the FDA's Office of New Animal Drug Evaluation, who with his wife, Mina, raises beef cattle, corn, soybeans, hay and "fancy" show chickens for breeding.

FDA officials recently decided to reconsider a ban in the wake of shock and outrage from Luther and other farmers who work at the FDA, many of whom have reported their farming to the agency through financial disclosures for years.

Enforcement of the ruling will be held in abeyance, FDA officials said late last month.

Luther's reprieve came in an Oct. 26 e-mail that Bernadette Dunham, director of the FDA'S Center for Veterinary Medicine, in which Luther works, sent to center employees. An FDA-wide e-mail recently followed and the FDA is looking at amending the regulations to allow greater flexibility for employees who own or work on family farms, Raymond Formanek, an FDA spokesman said.

The ruling means "I don't have to sell my farm this month, but they did not do this voluntarily," Luther said last week.

The FDA regulates contaminants, including levels of hormones and antibiotics, which can affect food for people and animals, as well as drugs for humans, livestock and pets. The U.S. Department of Agriculture regulates meat and poultry.

Luther, who planned to retire in January anyway, said he took up the fight for the next generation and for FDA employees who feared retribution if they spoke out.

"What we have are bunch of stupid people who don't have a clue about agriculture trying to regulate agriculture," said Luther, referring to lawyers and other officials who reinterpreted FDA ethics regulations and pronounced a ban. "This is not the fox guarding the henhouse; this fox doesn't even know what a henhouse is."

Agency officials said they do not know how many FDA employees could be affected by a ban on farming.

In the Center for Veterinary Medicine, as many as three dozen employees could be affected by the no-farming rule, Luther said. And many of those employees aren't retiring from the agency and therefore "can't walk away from" an issue that remains unsettled.

Katherine Weld — who could be affected by the ruling because she grows hay and raises meat goats in Frederick County, while supervising the review of generic animal drugs for approval at the FDA — said the FDA's judgment on the issue seemed "discriminatory and illogical."

The no-farming interpretation is based on a prohibition against most FDA employees having financial interests in a "significantly regulated organization," which is defined as an entity for which 10 percent or more of annual sales revenue comes from products that the FDA regulates.

FDA regulations make exceptions to allow physicians, veterinarians, dentists, pharmacists and nurses to work for "significantly regulated organizations," Weld noted in a letter to Department of Health and Human Services Secretary Kathleen Sebelius. The FDA is part of the Department of Health and Human Services.

The regulations appear to have been in the Supplemental Standards of Ethical Conduct for Employees of the Department of Health and Human Services for more than a decade.

"Even though these regulations have been in place for many years, there have been evolving legal interpretations on what constitutes an 'FDA-regulated product' as applied to farm crops and food animals," the FDA's ethics and integrity director, Vincent Tolino, wrote in an emailed response to The Gazette's questions, which was forwarded by the agency's public information office.

"There was really no exact point when an interpretation changed," Tolino wrote in another email. "Over time, many employees have raised questions about selling food and the Ethics and Integrity staff went to the FDA Office of the Chief Counsel for advice."

Weld, who holds a doctorate in animal science, said the work that she and many others do at the FDA while farming part-time "wouldn't give anyone a leg up."

Luther, who holds a doctorate in poultry science, said he has drawn support from the Maryland and Montgomery County Farm Bureaus, which sent letters to Sebelius.

"The commodity markets are extremely competitive, and it is impossible for an FDA employee to profit unethically from the sale of farm products — plant or animal," Montgomery Farm Bureau President George Lechliden wrote to Sebelius in an Oct. 15 letter.

Unlike selling stocks or bonds, it would be "nearly impossible" to sell a farm in 60 days, and doing so usually would result in the farmer selling his or her home, Lechliden wrote.

Weld and Luther said they still are worried because they haven't been shown the changes to the regulations the FDA is considering.

"The proposed amendment is in the conceptual stage and a final draft has not yet been developed," Formanek wrote in an e-mail response to The Gazette's request for the text.

The process is "detailed" and "there is no formal timeline," he said. The amendment is subject to approval of the Secretary of Health and Human Services and the Director of the Office of Government Ethics.

The "strongest advice" restricting FDA employees' investment in farming was issued in the "last few months" and "there have been ongoing questions and answers between FDA ethics , our legal counsel and center officials for the last 10 [to] 12 months," Tolino wrote in an e-mail.

Some FDA employees might already have taken losses because they sold or leased their land quickly, including some outside the Washington, D.C. region, Weld and Luther said. Their other options included removing themselves as an owner and officer of the farm operation and turning those jobs over to a spouse, or requesting an exception from a review board.

Luther said the fundamental assumptions that FDA ethics officials are making should be examined.

"It's just a mystery to me why they issued those rulings in the first place," he said.

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